Complete Summary

GUIDELINE TITLE

Osteoporosis.

BIBLIOGRAPHIC SOURCE(S)

Singapore Ministry of Health. Osteoporosis. Singapore: Singapore Ministry of Health; 2002 Feb. 63 p. [132 references]

GUIDELINE STATUS

This is the current release of the guideline.

COMPLETE SUMMARY CONTENT

SCOPE

DISEASE/CONDITION(S)

Osteoporosis

GUIDELINE CATEGORY

Diagnosis
Evaluation
Management
Prevention
Risk Assessment
Treatment

CLINICAL SPECIALTY

Endocrinology
Family Practice
Geriatrics
Internal Medicine
Obstetrics and Gynecology
Orthopedic Surgery
Rheumatology

INTENDED USERS

Advanced Practice Nurses
Allied Health Personnel
Dietitians
Physician Assistants
Physicians

GUIDELINE OBJECTIVE(S)

- To assist physicians in the diagnosis and management of osteoporosis
- To provide a review of the therapeutic agents available for the treatment of osteoporosis, with the aim of reducing fracture rates
- To aid primary care physicians in deciding when to refer patients with difficult problems to the relevant specialists
- To highlight areas where further research may be pursued

TARGET POPULATION

Patients with osteoporosis or at high risk for osteoporosis in Singapore.

INTERVENTIONS AND PRACTICES CONSIDERED

Diagnosis

1. Assessment based on the Osteoporosis Self-Assessment Tool for Asians (OSTA) and/or presence of other clinical risk factors or past fractures.
2. Bone mineral density (BMD) measurement using dual-energy X-ray absorptiometry (DXA) of hip and spine, single energy X-ray absorptiometry (SXA) of forearm or heel, ultrasound of the heel or tibia, and quantitative computed tomography (CT) scan.
3. Routine laboratory investigation to exclude diseases that mimic, cause or aggravate osteoporosis: relevant radiographs to document fractures, full blood count, erythrocyte sedimentation rate (ESR), creatinine, urinalysis, calcium, phosphate, liver function tests, and testosterone levels in men.
4. Optional testing including bone turnover markers, free thyroxine (T_4), thyroid stimulating hormone (TSH), intact parathyroid hormone (iPTH), 25-hydroxyvitamin D, follicle-stimulating hormone (FSH), luteinizing hormone (LH), prolactin, urinary free cortisol, dexamethasone suppression tests, tumour markers, myeloma screen, scintigraphic bone studies, and bone marrow examination.

Management

1. Life style modifications and non-pharmacological therapy, such as smoking cessation, weight-bearing exercises, moderation of alcohol consumption, maintenance of adequate intake of calcium and vitamin D, and environmental modifications to reduce the risk of falling or the degree of injury from falls.
2. Therapeutic interventions based on factors that include fracture risk, past fracture, BMD, age, and risk for falls/bone loss and diagnostic BMD thresholds as treatment thresholds.
3. Preventive drug interventions including hormone replacement therapy (HRT), raloxifene, tibolone, alendronate, risedronate, etidronate, calcitonin, ipriflavone.
4. Therapeutic drug interventions including alendronate, risedronate, etidronate, clodronate, zoledronate, hormone replacement therapy, raloxifene, calcitonin, calcitriol, alfacalcidol, calcium and vitamin D, anabolic steroids, ipriflavone, parathyroid hormone, fluoride.
5. Lumbar spine BMD measurement after more than one year of treatment and bone turnover markers at baseline and 3 to 6 month intervals to assess therapeutic response.
6. Specialist referral for premenopausal and male patients, patients on long-term steroids, patients with disproportionately low Z scores, patients with endocrine or metabolic bone disease, and patients with other causes of pathological fracture.

MAJOR OUTCOMES CONSIDERED

- Bone mineral density
- Osteoporotic fracture risk
- Fracture rate
- Disease mortality
- Disease morbidity
- Quality of life

METHODOLOGY

METHODS USED TO COLLECT/SELECT EVIDENCE

Searches of Electronic Databases

DESCRIPTION OF METHODS USED TO COLLECT/SELECT THE EVIDENCE

Not stated

NUMBER OF SOURCE DOCUMENTS

Not stated

METHODS USED TO ASSESS THE QUALITY AND STRENGTH OF THE EVIDENCE

Weighting According to a Rating Scheme (Scheme Given)

RATING SCHEME FOR THE STRENGTH OF THE EVIDENCE

Levels of Evidence

Ia Evidence obtained from meta-analysis of randomised controlled trials.

Ib Evidence obtained from at least one randomised controlled trial.

IIa Evidence obtained from at least one well-designed controlled study without randomisation.

IIb Evidence obtained from at least one other type of well-designed quasi-experimental study.

III Evidence obtained from well-designed non-experimental descriptive studies, such as comparative studies, correlation studies and case studies.

IV Evidence obtained from expert committee reports or opinions and/or clinical experiences of respected authorities.

METHODS USED TO ANALYZE THE EVIDENCE

Review of Published Meta-Analyses
Systematic Review

DESCRIPTION OF THE METHODS USED TO ANALYZE THE EVIDENCE

Not stated

METHODS USED TO FORMULATE THE RECOMMENDATIONS

Not stated

RATING SCHEME FOR THE STRENGTH OF THE RECOMMENDATIONS

Grades of Recommendation

Grade A (evidence levels Ia, Ib) Requires at least one randomised controlled trial as part of the body of literature of overall good quality and consistency addressing the specific recommendation.

Grade B (evidence levels IIa, IIb, III) Requires availability of well conducted clinical studies but no randomised clinical trials on the topic of recommendation.

Grade C (evidence level IV) Requires evidence obtained from expert committee reports or opinions and/or clinical experiences of respected authorities. Indicates absence of directly applicable clinical studies of good quality.

GPP (good practice points) Recommended best practice based on the clinical experience of the guideline development group.

COST ANALYSIS

A formal cost analysis was not performed and published cost analyses were not reviewed.

METHOD OF GUIDELINE VALIDATION

Peer Review

DESCRIPTION OF METHOD OF GUIDELINE VALIDATION

These guidelines were reviewed at a consensus workshop meeting, finalized and published.

RECOMMENDATIONS

MAJOR RECOMMENDATIONS

Each recommendation is rated based on the levels of the evidence and the grades of recommendation. Definitions of the grades of the recommendations (A, B, C, Good Practice Points) and levels of the evidence (Level I- Level IV) are presented at the end of the Major Recommendations field.

Diagnosis of Osteoporosis

C - Osteoporosis is defined either by the presence of a fragility fracture or a bone mineral density (BMD) measurement which falls below a threshold level arbitrarily set at 2.5 S.D. below the mean peak bone mass of young adults. (Grade C, Level IV)

C - The most validated BMD technique and site of choice for the diagnosis of osteoporosis is duel-energy x-ray absorptiometry (DXA) measured at the hip. DXA of the spine is generally the best site to monitor response to therapy. However, in older women where aortic calcification or facet joint arthritis may confound spine BMD, the hip measurement would be preferable for monitoring purposes. Repeat evaluations should be done no less than a year apart. (Grade C, Level IV)

C - Considering the increasing number of elderly who are at risk for osteoporosis which is often silent and balancing this against the cost of BMD, the case-finding strategy for detecting osteoporosis is preferred to a population screening strategy. This involves clinically evaluating individuals for their risk of having osteoporosis, and measuring BMD in those at highest risk. Tools such as the Osteoporosis Self-Assessment Tool for Asians (OSTA) or National Osteoporosis Foundation (NOF) guidelines may be used as an initial filter for categorizing individuals by osteoporosis risk, with further decision-making based on the presence of other clinical risk factors or past fractures to determine who should have BMD measurements. (Grade C, Level IV)

Management of Osteoporosis

C - Generally, the population should be encouraged to adopt strategies which may decrease the risk of osteoporosis such as maintaining a healthy lifestyle of good

nutrition (particularly adequate calcium intake), regular weight-bearing exercise, cessation of smoking and avoiding excessive alcohol consumption. Consideration should be given to modifying the environment to reduce the risk of falling or the degree of injury from falls. Healthy lifestyle strategies should start from a young age to optimize the conditions for building up peak bone mass. (Grade C, Level IV)

A - Patients with established osteoporosis should be considered for treatment with drugs shown to reduce the risk of the first fracture or further fractures since the data with regard to the effectiveness of these drugs is strong. The decision to institute treatment should be guided by an integration of fracture risk which includes considering the patient´s age, BMD, and other risk factors for fracture, falls or bone loss. The choice of therapy would depend on the relative anti-fracture efficacy of available drugs, other non-skeletal benefits, contraindications, side effects, cost and convenience, and whether the patient has contraindications to using the drug. (Grade A, Level Ia & Ib)

A - Patients without fracture but with osteopenia may be considered for treatment. However, it must be borne in mind that the risk of fracture among this large group of usually younger women is relatively low, and the pattern of fracture differs from older women, with more wrist and vertebral and less hip fractures. In addition, the most important measure of the effectiveness of any therapeutic measure remains anti-fracture efficacy, and thus far, most therapies initiated in osteopenic patients have not been shown to reduce fracture risk. (Grade A, Level Ib)

C - Special instances of osteoporosis, such as in premenopausal women, men and in patients on corticosteroids, may require assessment and management at specialist osteoporosis clinics. (Grade C, Level IV)

Definitions:

Grades of Recommendation

Grade A (evidence levels Ia, Ib) Requires at least one randomised controlled trial as part of the body of literature of overall good quality and consistency addressing the specific recommendation.

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Grade C (evidence level IV) Requires evidence obtained from expert committee reports or opinions and/or clinical experiences of respected authorities. Indicates absence of directly applicable clinical studies of good quality.

GPP (good practice points) Recommended best practice based on the clinical experience of the guideline development group.

Levels of Evidence

Ia Evidence obtained from meta-analysis of randomised controlled trials.

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IIb Evidence obtained from at least one other type of well-designed quasi-experimental study.

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IV Evidence obtained from expert committee reports or opinions and/or clinical experiences of respected authorities.

CLINICAL ALGORITHM(S)

The original guideline contains a clinical algorithm for the management of osteoporosis.

EVIDENCE SUPPORTING THE RECOMMENDATIONS

TYPE OF EVIDENCE SUPPORTING THE RECOMMENDATIONS

The type of supporting evidence is identified and graded for each recommendation (see "Major Recommendations").

BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS

POTENTIAL BENEFITS

Improved management of osteoporosis and prevention of osteoporotic fractures and other osteoporotic complications

POTENTIAL HARMS

Hormone Replacement Therapy (HRT)

There may be a small increase in the risk of breast cancer and venous thromboembolism with the use of HRT. It is generally accepted that giving HRT for periods of up to 10 years would not increase the risks of HRT significantly, but risks and benefits of HRT should still be explained to women so that an informed decision can be made concerning its use.

Raloxifene

Raloxifene, a selective estrogen receptor modulator (SERM), prevents bone loss but does not reduce, and may worsen menopausal symptoms. Raloxifene appears to decrease the risk of breast cancer and cardiovascular events in women with

high cardiovascular risk, but is associated with an increased risk of thromboembolism.

QUALIFYING STATEMENTS

QUALIFYING STATEMENTS

- This guideline is not intended to serve as a standard of medical care. Standards of medical care are determined on the basis of all clinical data available for an individual case and are subject to change as scientific knowledge advances and patterns of care evolve.
- The contents of this guideline document are guidelines to clinical practice, based on the best available evidence at the time of development. Adherence to this guideline may not ensure a successful outcome in every case, nor should it be construed as including all proper methods of care or excluding other acceptable methods of care. Each physician is ultimately responsible for the management of his/her unique patient in the light of the clinical data presented by the patient and the diagnostic and treatment options available.

IMPLEMENTATION OF THE GUIDELINE

DESCRIPTION OF IMPLEMENTATION STRATEGY

In addition to disease prevention, treatment and rehabilitation, health care professionals need to promote behavioral changes necessary for healthier living through health education and reshaping of the environment. The Singapore Ministry of Health is working on strategies to increase the awareness of osteoporosis amongst the public and professional groups, as well as to increase the professional capabilities suitable for the management of osteoporosis.

It is envisaged that this set of guidelines will assist the doctors in Singapore to assess and manage patients with osteoporosis more effectively. In particular, medical practitioners in primary care, play a crucial role in reinforcing the healthy lifestyle message to patients.

It is hoped that doctors will incorporate these guidelines into their clinical practice and by so doing, further improve the overall management of osteoporosis and the prevention of its consequences.

IMPLEMENTATION TOOLS

Clinical Algorithm

For information about availability, see the "Availability of Companion Documents" and "Patient Resources" fields below.

INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT CATEGORIES

IOM CARE NEED

Living with Illness
Staying Healthy

IOM DOMAIN

Effectiveness
Patient-centeredness

IDENTIFYING INFORMATION AND AVAILABILITY

BIBLIOGRAPHIC SOURCE(S)

Singapore Ministry of Health. Osteoporosis. Singapore: Singapore Ministry of Health; 2002 Feb. 63 p. [132 references]

ADAPTATION

Not applicable: The guideline was not adapted from another source.

DATE RELEASED

2002 Feb

GUIDELINE DEVELOPER(S)

Singapore Ministry of Health - National Government Agency [Non-U.S.]

SOURCE(S) OF FUNDING

Singapore Ministry of Health (MOH)

GUIDELINE COMMITTEE

Workgroup on Osteoporosis

COMPOSITION OF GROUP THAT AUTHORED THE GUIDELINE

Workgroup Members: Dr Leonard Koh (Chairman); Dr Leong Keng Hong; Dr Koh Ee Tzun; Dr David Ng; Dr Noor Hafizah; Dr C Rajasoorya; Dr Saw Seang Mei; Dr Shamal Das De; Dr Tan Seang Beng; Dr Tay Boon Lin; Dr Yu Su Ling; Ms Louisa Zhang

FINANCIAL DISCLOSURES/CONFLICTS OF INTEREST

Not stated

GUIDELINE STATUS

This is the current release of the guideline.

GUIDELINE AVAILABILITY

Electronic copies: Available in Portable Document Format (PDF) from the Singapore Ministry of Health Web site.

Print copies: Available from the Singapore Ministry of Health, College of Medicine Building, Mezzanine Floor 16 College Rd, Singapore 169854.

AVAILABILITY OF COMPANION DOCUMENTS

None available

PATIENT RESOURCES

None available

NGC STATUS

This NGC summary was completed by ECRI on May 20, 2003. The information was verified by the guideline developer on June 3, 2003.

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